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mailed  
DEC 6 2012  
by OLA

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,693,326 was filed on August 09, 2012, under 35 U.S.C. § 156. Please note that a patent term extension application for U.S. Patent No. 5,955,079 for BLA, BL-125363/0 for the human drug product MENHIBRIX™ was filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, MENHIBRIX™, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

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